

SUBJECT TO MOTION TO EXCEED PAGE AND WORD LIMIT

**IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA)	
)	
<i>Plaintiff,</i>)	
)	
v.)	Civil Action No. 5:22-cv-05055-JFM
)	
INHANCE TECHNOLOGIES, LLC,)	
)	
<i>Defendant.</i>)	

**MEMORANDUM OF INTERVENOR-PLAINTIFFS IN SUPPORT OF
THEIR MOTION FOR SUMMARY JUDGMENT AND ENTRY OF AN
INJUNCTION AGAINST DEFENDANT INHANCE**

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Intervenor-plaintiffs submit this Memorandum in support of their motion for summary judgment and entry of an injunction against defendant Inhance Technologies LLC (“Inhance”). This injunction would direct Inhance to immediately cease ongoing violations of the Toxic Substances Control Act (“TSCA”) that are causing serious and irreversible harm to public health.

Attached is a Statement of Undisputed Material Facts (“SUMF”) warranting the entry of summary judgment for intervenor-plaintiffs and an injunction against defendant Inhance. Also attached is an Appendix compiling the Exhibits on which this motion is based.

STATEMENT OF THE CASE

I. The Parties

Intervenor-plaintiffs Center for Environmental Health (“CEH”) and Public Employees for Environmental Responsibility (“PEER”) are non-profit organizations headquartered in Oakland, California, and Silver Spring, Maryland, who are dedicated to protecting the public from environmental and health hazards and promoting a high standard of environmental ethics, scientific integrity, and legal accountability. *See* SUMF ¶¶ 1, 2 [Exs. 2, 4-5 Decls. of Kaya Sugarman, Timothy Whitehouse, and Kyla Bennett at A-11 ¶ 7, A-22 ¶ 3, A-45 ¶ 3]. Intervenor-plaintiff Jay De La Rosa, a furniture maker and do-it-yourself car mechanic in Los Angeles, California, is concerned about his ongoing exposure to toxic substances from plastic containers he uses on a daily basis. *See* SUMF ¶ 7 [Ex. 3, Decl. of Jay De La Rosa at A-16 ¶¶ 1-2].

Headquartered in Houston, Texas, defendant Inhance treats high-density polyethylene (“HDPE”) and other plastic containers by “fluorination,” a process in which fluorine gas is applied to the container under high temperatures to impart barrier properties to the plastic. *See* SUMF ¶ 10 [Ex. 8, SNUN Attachment Number: 011 at A-209]. Inhance is the only provider of post-mold fluorination services to U.S. manufacturers, distributors, and users of plastic

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packaging. At eleven U.S. facilities,¹ it fluorinates over 200 million containers and other items each year. *See* SUMF ¶ 14 [Ex. 20, Fluoro-Seal International, LLC, Making the Impossible Possible at A-634]. Following treatment, the containers are shipped to Inhance customers and, after being filled with products, are distributed throughout the economy for a wide range of industrial, commercial, and consumer uses.

II. EPA’s 2020 Significant New Use Rule Prohibiting Certain PFAS

Per- and Polyfluoroalkyl substances (“PFAS”) have raised deep concern around the globe because of their persistence, prevalence in people, wildlife, and the environment, and harmful effects on human health and ecosystems. On July 27, 2020, the U.S. Environmental Protection Agency (“EPA”) issued a significant new use rule (“SNUR”) under section 5(a) of TSCA, 15 U.S.C. § 2604(a), restricting a subset of PFAS called long-chain perfluoroalkyl carboxylate (“LCPFAC”) substances. 85 Fed. Reg. 45109 (July 27, 2020), 40 C.F.R. § 721.10536. These substances include the highly toxic perfluorooctanoic acid (“PFOA”) and several other PFAS that were phased out by agreement between EPA and their major manufacturers following evidence of widespread environmental contamination and serious health impacts to exposed communities.

The SNUR prohibits production of PFOA and other LCPFACs unless the manufacturer has submitted Significant New Use Notices (“SNUNs”) and EPA has completed a comprehensive review of the health and environmental effects of the proposed new use. Under section 5(a)(3) of TSCA, 15 U.S.C. § 2604(a)(3), the use is barred unless EPA has determined

¹ These facilities are located in Allentown, Pennsylvania; Forest Park, Georgia; Homerville, Georgia; Centerville, Iowa; Mt. Pleasant, Iowa; West Chicago, Illinois; Columbus, Ohio; Houston, Texas; St. Louis, Missouri; Yuma, Arizona; and Troy, Alabama. *See* SUMF ¶ 11 [Ex. 49 Subpoena Response at A-1209].

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that it is unlikely to present an unreasonable risk. Otherwise, EPA must enter an order under section 5(e) or section 5(f) of TSCA imposing restrictions necessary to protect health and the environment. 15. U.S.C. § 2604(e)-(f).

III. Inhance's Deliberate Violations of the LCPFAC SNUR

It is undisputed that Inhance's fluorination process forms nine LCPFACs subject to the SNUR and four shorter-chain perfluoroalkyl carboxylic acids ("PFCAs") with known harmful effects. *See* SUMF ¶¶ 98, 99 [Ex. 7, Decl. of Jimena Diaz Leiva at A-152, Ex. 6, Jamie DeWitt and Drake Phelps Report at A-68]. Thus, once the SNUR took effect on September 24, 2020, Inhance was obligated under TSCA to cease production of these LCPFACs and submit SNUNs. However, it continued to fluorinate containers in violation of the SNUR and is doing so today.

EPA learned of the presence of LCPFACs in fluorinated containers in late 2020. The Agency launched a lengthy investigation and conducted testing confirming the formation of LCPFACs during fluorination. In March of 2022, the Agency put Inhance on notice that it was in violation of the SNUR. Government Complaint (ECF 3) ¶¶ 40-42. Based on this determination, EPA advised Inhance and publicly announced that LCPFACs could not be produced unless SNUNs were submitted complying with TSCA SNUR requirements and the Agency determined that the LCPFACs were unlikely to present an unreasonable risk of injury. *See* SUMF ¶ 59 [Ex. 27, EPA Open Letter to Industry at A-742-43, Ex. 46, EPA Continues to Take Actions to Address PFAS in Commerce at A-1181].

Finally, on December 30, 2022, over two years after Inhance's SNUR violations came to light, EPA received from Inhance nine consolidated SNUNs for LCPFACs subject to the SNUR. 88 Fed. Reg. 10320 (Feb. 17, 2023). Nine additional SNUNs were received on March 7-8, 2023. 88 Fed. Reg. 24416 (Apr. 20, 2023). EPA is still reviewing the SNUNs.

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IV. Enforcement Actions filed by Intervenor-Plaintiffs and the United States

On October 21, 2022, under TSCA section 20(b)(1), intervenor-plaintiffs CEH and PEER sent a notice of intent to sue to defendant Inhance and EPA Administrator Michael Regan. Jay de la Rosa sent an identical notice to Inhance and to EPA on November 17, 2022. Intervenor-plaintiffs' Complaint, ECF 36 at ¶¶ 56-61. Following receipt of these 60-day notices, the United States filed a Complaint against Inhance in this Court on December 19, 2022. ECF 3. Eight days later, intervenor-plaintiffs sued Inhance in the District Court for the District of Columbia under the citizens' suit provisions in TSCA section 20(a). *Ctr. for Env't. Health et al. v. Inhance Techs. USA*, Civ. A. No. 22-03819 (D.D.C. Dec. 27, 2022). Based on the "diligent prosecution" bar in TSCA section 20(b)(1)(B), Judge Boasberg of that court dismissed this case without prejudice on April 6, 2023. ECF 25. Plaintiffs then exercised their right to intervene in the Government's case under section 20(b)(1)(B) of TSCA, and this Court granted their unopposed motion to intervene on April 26, 2023. ECF 33.

SUMMARY OF GROUNDS FOR ENJOINING INHANCE'S TSCA VIOLATIONS

There is ample support in the record, TSCA requirements, and case law for granting summary judgment to intervenor-plaintiffs and restraining Inhance from continuing to violate TSCA and the LCPFAC SNUR:

- Intervenor-plaintiffs' declarations establish that they have suffered concrete injuries stemming from Inhance's continuing violations of TSCA. These injuries are a direct result of Inhance's violations of the SNUR and would be redressed by enjoining these violations. Intervenor-plaintiffs thus possess Article III constitutional standing. Even without demonstrating standing, intervenor-plaintiffs could prosecute this case based on the standing of plaintiff United States.

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- Inhance admits in its SNUNs that LCPFACs are present in fluorinated plastic containers and their contents and are formed by chemical reactions during the Inhance in-mold fluorination process. The presence of these substances in fluorinated containers is confirmed by extensive test data. Accordingly, Inhance's ongoing manufacture and processing of LCPFACs comprise a "significant new use" under the July 2020 SNUR and Inhance is in violation of the SNUR. This violation constitutes a "prohibited act" under TSCA section 15 and is subject to enforcement by the United States and citizens under TSCA sections 17 and 20.
- Once the Agency informed Inhance on March 1, 2022, that its formation of LCPFACs during fluorination constituted unlawful manufacture and processing of these substances, EPA SNUR regulations at 40 C.F.R. § 721.5(d)(1) required it to cease supplying fluorinated containers to its customers or notify them of the SNUR requirements and obtain written assurance of their compliance. Defendant's ongoing failure to take these actions not only a separate violation of the LCPFAC SNUR and 40 C.F.R. Part 721, but also comprises a "prohibited act" under TSCA section 15.
- The two TSCA enforcement provisions applicable to this case – sections 17 and 20, 15 U.S.C. §§ 2616 and 2619 – authorize a targeted set of remedies restraining ongoing violations of the law. Under Supreme Court decisions, this Court's task is to choose a remedy that will achieve compliance with TSCA. Once the Court concludes that Inhance is in violation of TSCA, it lacks discretion to conclude that a remedy compelling compliance is unnecessary and the violation should continue unabated. The choice of a remedy should be made without consideration of the usual factors for injunctive relief, including a showing of irreparable harm or balancing the equities.

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- Since the formation of LCPFACs during fluorination is unlawful under the 2020 SNUR, the injunction issued by the Court must ensure that Inhance immediately stops producing and processing LCPFACs during the fluorination of plastic containers until and unless EPA completes its review of Inhance's SNUNs and expressly permits these activities. Inhance must also be ordered to cease supplying fluorinated containers to its customers or notify them of the SNUR requirements, obtain written assurance of their compliance and provide it to EPA. No other remedies would be effective in ensuring compliance with TSCA.
- Where a statutory violation is knowing and willful, courts grant injunctive relief without a traditional balancing of equities. Here, there is compelling undisputed evidence that Inhance has deliberately chosen to manufacture LCPFACs even after it was informed by EPA that it was in violation of TSCA and the Agency advised that LCPFAC manufacture could not continue without full compliance with the SNUR.
- Even where courts employ the traditional four factors to consider the propriety of injunctive relief to restrain statutory violations, these factors must be applied in light of the public interest purposes of the statute. Under environmental laws, injuries to public health are considered irreparable and the public interest, as well as the balance of equities, generally favor injunctive relief to protect against harm.
- In this case, nine uniquely dangerous LCPFACs and four shorter chain PFCAs known to cause multiple harmful effects were found in fluorinated containers and their contents. According to the latest EPA science, at least one and possibly several of these LCPFACs have no safe level of exposure. Over 200 million containers and other items are fluorinated each year and used to package numerous consumer, commercial, and industrial products distributed throughout the economy. The best available science shows that, at the levels

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present in these containers, a large segment of the US population is at risk of harm. An injunction immediately halting the production of PFAS during fluorination process is essential to prevent this harmful exposure and protect public health.

SUMMARY JUDGMENT STANDARD

A trial court shall enter summary judgment if, after a review of all evidentiary material in the record, “there is no genuine issue as to any material facts, and the moving party is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 324 (1986); *White v. Westinghouse Electric Co.*, 862 F.2d 56, 59 (3d Cir. 1988). The evidence presented must be viewed in the light most favorable to the nonmoving party. *White*, 862 F.2d at 59. The moving party has the initial burden of identifying evidence which it believes shows an absence of a genuine issue of material fact. *Celotex Corp.*, 477 U.S. at 324.

Once the moving party satisfies its burden, the burden shifts to the nonmoving party, which must go beyond its pleading and designate specific facts by use of declarations and other evidence showing there is a genuine issue for trial. *Id.*

ARGUMENT

I. PLAINTIFF-INTERVENORS HAVE STANDING

In order for intervenor-plaintiffs to prosecute their claims, it is only necessary that *one* of the plaintiffs have standing. *Massachusetts v. EPA*, 549 U.S. 497, 518 (2007). There is no dispute that the United States has standing in this case. In addition, intervenor-plaintiffs possess Article III constitutional standing in their own right. Plaintiff Jay De La Rosa has individual standing while plaintiff organizations PEER and CEH have associational standing.

The basic requirement for standing, whether for an organization or an individual, is a “concrete and particularized injury that is either actual or imminent,” which is fairly traceable to the defendant, and it is likely that a favorable decision will redress that injury. *Lujan v.*

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Defenders of Wildlife, 504 U.S. 555, 560-61 (1992). Plaintiff-Intervenors have established through their declarations that they have suffered concrete injuries stemming from Inhance's continuing violations of TSCA. Furthermore, these injuries to the plaintiff-intervenors are a direct result of Inhance's violation of the LCPFAC SNUR, 40 C.F.R. § 721.10536, and would directly be redressed by Inhance's compliance with TSCA.

A. Plaintiff-Intervenor Jay De La Rosa Has Article III Standing

Jay De La Rosa meets the requirements for Article III standing as he is at risk of an actual and imminent injury, traceable to Inhance, that the court could remedy.

An injury in fact must be "(a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical." *Friends of the Earth v. Laidlaw Env'tl. Services*, 528 U.S. 167, 180-81 (2000). For years, Mr. De La Rosa has come into extensive contact with potentially fluorinated plastic containers while working to restore furniture and repair cars. *See* SUMF ¶ 7 [Ex. 3 at A-16 ¶¶ 1-4]. When he uses the products stored in these containers, Mr. De La Rosa handles the container and its contents and breathes the fumes they release. *See* SUMF ¶ 8 [Ex. 3 at A-17 ¶ 5]. Mr. De La Rosa is concerned that he may be exposed to LACPFC chemicals with negative health impacts. *See* SUMF ¶ 9 [Ex. 3 at A-17-18 ¶¶ 5,7]. However, he cannot ascertain which containers are fluorinated and which are not or switch to non-plastic containers, so he cannot protect himself from LACPFCs. *Id.*

Mr. De La Rosa's fear and anxiety surrounding his own health and wellbeing show an actual, imminent, and particularized injury that is fairly traceable to Inhance's failure to comply with the LACPFC SNUR and TSCA. To meet this requirement, a plaintiff need only show that "there is a 'substantial likelihood' that defendant's conduct caused the plaintiffs' harm."

PennEnvironment & Sierra Club v. Genon Ne. Mgmt. Co., 2011 U.S. Dist. LEXIS 29098, *21,

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*73 (W.D.P.A. Mar. 21, 2011) (quoting *Pub. Interest Research Grp. v. Powell Duffryn Terminals, Inc.*, 913 F.2d 64, 72 (3d Cir. 1990)). Here, Inhance is the only post-mold fluorinator of plastic containers in the United States, creating a high probability that Mr. De La Rosa comes into contact with plastic containers fluorinated by Inhance.

Lastly, there is “a likelihood that the requested relief will redress the alleged injury.” *Steel Co. v. Citizens for a Better Env’t*, 523 U.S. 83, 103 (1998). Mr. De La Rosa’s injury results from Inhance’s continued unlawful manufacture of LCPFAC substances before EPA can evaluate their risks and restrict or prohibit fluorination to protect human health. Stopping PFAS production during EPA’s SNUN review will significantly reduce Mr. De La Rosa’s exposure to these substances while EPA completes its SNUR review.

B. Plaintiffs PEER and CEH Meet Associational Standing Requirements

To demonstrate associational standing, an organization must show: (1) “[i]ts members would otherwise have standing to sue in their own right;” (2) the “interests it seeks to protect are germane to the organization’s purpose; and” (3) “[n]either the claim asserted nor the relief requested requires participation of individual members in the lawsuit.” *Hunt v. Wash. State Apple Adver. Comm’n*, 432 U.S. 333, 343 (1977). Intervenor-plaintiffs meet these requirements.

First, the interests they seek to protect in seeking to require Inhance’s compliance with the LCPFAC SNUR are germane to these organizations’ purposes. PEER’s purposes include assisting those who speak out on behalf of environmental ethics and protecting the integrity of individual employees and scientists within the government who dissent for ethical reasons. *See* SUMF ¶ 1 [Ex. 4 at A-22 ¶ 3, Ex. 5 at A-45 ¶ 3]. CEH’s mission “is to protect people from toxic chemicals by working with communities, consumers, workers, government, and the private sector to demand and support business practices that are safe for public health and the

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environment.” *See* SUMF ¶ 2 [Ex. 2 at A-11 ¶ 7]. These organizational purposes are directly served by the aim of this lawsuit, to require Inhance to comply with TSCA.

Second, it is apparent that neither the claim asserted (the failure to comply with the LCPFAC SNUR) nor the relief requested (compliance with the LCPFAC SNUR and TSCA) requires the participation of the individual members in the lawsuit. Inhance’s claimed failure to comply with its statutory obligations under TSCA is not specific to the individual organizational members, and the declaratory and injunctive relief sought would address the members’ injuries without any individualized relief. *See Hunt*, 432 U.S. at 343 (“If in a proper case the association seeks a declaration, injunction, or some other form of prospective relief, it can reasonably be supposed that the remedy, if granted, will inure to the benefit of those members of the association actually injured”).

Finally, leaders of these organizations would have standing to sue in their own right. Here, PEER’s Executive Director and member of its Board of Directors, Tim Whitehouse, and PEER’s Northeast and Mid-Atlantic Director and Director of Science Policy, Kyla Bennett, are directly impacted by the risk of exposure to LCPFACs and suffer fear and anxiety about the high risk of exposure to LCPFAC chemicals from fluorinated containers. *See* SUMF ¶ 3 [Ex. 4 at A-24-25 ¶ 11, Ex. 5 at A-48 ¶ 14]. Similarly, CEH’s Board Member José Bravo and Director of Illegal Toxic Threats Kaya Sugarman have been personally impacted by the failure of Inhance to comply with the LCPFAC SNUR and fear the high risk of exposure to LCPFACs from fluorinated plastics. *See* SUMF ¶ 5 [Ex. 1 at A-6-7 ¶ 9, Ex. 2 at A-10-11 ¶ 5]. Mr. Whitehouse, Dr. Bennett, Mr. Bravo, and Ms. Sugarman have, for years, come into contact with numerous potentially fluorinated plastic containers and their contents. *See* SUMF ¶¶ 2, 5 [Ex. 4 at A-24 ¶ 10, Ex. 5 at A-47-48 ¶ 11, 12, Ex. 1 at A-6 ¶ 8, Ex. 2 at A-10 ¶ 3]. *See* SUMF ¶¶ 2, 5 [Ex. 4 at A-

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24-25 ¶ 11, Ex. 5 at A-48 ¶ 15, Ex. 1 at A-6-7 ¶ 9, Ex. 2 at A-10-11 ¶ 5]. Although declarants experience anxiety due to the dangers of LCPFACs to their health and communities, *see* SUMF ¶¶ 3, 6 [Ex. 4 at A-24-25 ¶ 11, Ex. 5 at A-48 ¶ 14, Ex. 1 at A-6-7 ¶ 9, Ex. 2 at A-10 ¶ 3], they lack the ability to protect themselves because they have cannot determine which containers contain these chemicals, and some products they need are not available in non-plastic containers. Thus, they are at increased risk from Inhance’s failure to submit a timely SNUN and its continued manufacture of these substances. *PennEnvironment*, 2011 U.S. Dist. LEXIS 29098 at *73. If Inhance were required to comply with TSCA and the LCPFAC SNUR, these declarants would have substantially less chance of coming into contact with LCPFACs when using plastic containers and their contents and their fear and anxiety about such contact would be lessened.

Therefore, Plaintiffs PEER and CEH meet the requirements of associational standing based on the injuries to their members.

II. INHANCE’S ONGOING MANUFACTURE AND PROCESSING OF PFAS DURING FLOUORINATION VIOLATE TSCA

A. The LCPFAC SNUR Prohibits Manufacture and Processing of LCPFACs Without Compliance with the SNUR Requirements in TSCA and EPA Regulations

The guiding premise of the TSCA SNUR provisions is that “[t]he most effective and efficient time to prevent unreasonable risks to public health or the environment is prior to first manufacture.” S. Rep. 94-698, at 5 (1976), *as reprinted in* 1976 U.S.C.C.A.N. 4491, 4495. Reflecting this principle, section 5(a)(2) of TSCA, 15 U.S.C. § 2604(a)(2), authorizes EPA to designate by rule certain uses of chemical substances as “significant new uses.” Under section 5(a)(1)(A)(ii), “no person may manufacture or process any chemical substance for a use which the Administrator has determined . . . is a significant new use” without complying with the requirements of section 5(a)(1)(B). Under this provision, the manufacturer or processor must

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submit a notice to EPA of its intent to manufacture or process the substance for the significant new use at least 90 days before these activities will be initiated.

Manufacture or processing of the SNUN substance cannot begin until (1) EPA reviews the notice, (2) makes a risk determination for the substance under section 5(a)(3), and (3) based on that determination, issues an order imposing restrictions under sections 5(e) or 5(f) where necessary to eliminate any unreasonable risk that the substances does or may present.² Under section 5(a)(1)(B)(i), firms subject to that order may only begin manufacture or processing of the SNUR substance *after* the order is issued and in compliance with its requirements. The substance may be manufactured or processed without restriction only if EPA determines under section 5(a)(3)(C) of TSCA that it is not likely to present an unreasonable risk to human health or the environment.

On July 27, 2020, EPA finalized the LCPFAC SNUR. 85 Fed. Reg. 45109. The SNUR “requires persons to notify EPA at least 90 days before commencing the manufacture (including import) or processing of these chemical substances for the significant new uses described in this notice.” The SNUR states that “[m]anufacturing (including import) or processing [of LCPFACs] for the significant new use are prohibited from commencing until EPA has conducted a review of the notice, made an appropriate determination on the notice,

² An order under section 5(e) of TSCA is necessary if EPA makes one of three findings under section 5(a)(3)(B): (i) the use may present an unreasonable risk of injury, (ii) there is insufficient information for a reasoned evaluation of the use’s health or environmental effects, or (iii) the substance is or will be produced in substantial quantities for the use and either enters or may reasonably be anticipated to enter the environment in substantial quantities or give rise to significant or substantial human exposure. An order under section 5(f) is necessary where EPA determines under section 5(a)(3)(A) that the new chemical or new use “presents an unreasonable risk of injury to health or the environment.” Under both section 5(e) and 5(f), EPA’s risk determinations cannot consider “costs or other nonrisk factors.”

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and taken such actions are required in association with that determination.” 85 Fed. Reg. at 45110.³

B. There Is No Dispute that the Inhance Fluorination Process Results in the Presence of LCPFACs in Plastic Containers and their Contents

In its SNUNs, Inhance admits that “[t]he fluorination of HDPE containers unintentionally forms small amounts of LCPFACs. This is the result of fluorination of carboxylic acids formed during the processing of HDPE during molding, prior to molding.” *See* SUMF ¶ 29 [Ex. 8 at A-212]. As the SNUNs explain:

The fuel tank and fuel container manufacturing process involves the heating and then extrusion of HDPE resin in the presence of oxygen prior to shaping the HDPE into fuel tanks and fuel containers. This heating and extrusion causes some of the HDPE resin to break down into carboxylic acids and certain other lower-molecular weight species. The fluorination process exposes those carboxylic acids and other species, along with the HDPE itself, to fluorine gas (F₂). The HDPE reacts with the fluorine to form a layer of fluoropolymer, which acts as the barrier needed to prevent permeation of fuel. At the same time, the carboxylic acids react with the fluorine also, unintentionally forming LCPFACs. Much of the LCPFACs remain in the barrier layer of the fuel tanks and fuel containers, but some amounts may be expected to migrate into the fuel contained in those tanks and containers over time.

See SUMF ¶ 29 [Ex. 8 at A-209]. Thus, the SNUNs recognize that “an apparently unavoidable aspect of fluorination of HDPE containers” is the production of PFAS and “there is no easy solution to the problem of [PFAS] formation.” *Id.*

Multiple studies by EPA, other researchers and Inhance itself have consistently found the presence of several LCPFACs and short-chain PFCAs in fluorinated containers and their

³ The SNUR explains that the “term LCPFAC refers to the long-chain category of perfluorinated carboxylate chemical substances with perfluorinated carbon chain lengths equal to or greater than seven carbons and less than or equal to 20 carbons. *Id.* LCPFACs are in turn part of the group of perfluoroalkyl carboxylic acids (“PFCAs”), which includes the short-chain carboxylates that are also found in fluorinated containers but are not subject to the SNUR.

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contents. These studies are described in the declaration of Dr. Jimena Diaz Leiva, CEH's Science Director. *See* SUMF ¶ 35 [Ex. 7 at A-139-40 ¶ 4].

Looking at the data as a whole, Dr. Leiva concludes that:

There is a high level of concurrence amongst the results from these studies. For PFOA, the concentrations of this analyte measured in extracts from fluorinated HDPE containers and in different solvents held in these containers, are all comparable across studies where specific analyte concentrations are reported (Table 2). Moreover, the evidence from these studies indicates that hazardous PFCAs are readily able to leach from HDPE containers into their contents. Chemically and materially distinct solvents like methanol, acetone, and water, as well as household products and foodstuffs like insecticides, carpet cleaners, and mayonnaise, have all been shown to contain PFCAs from fluorinated containers. Adding to the risk of exposure for consumers, over time, the concentration of PFCAs in the contents of these containers increases due to continual leaching from the containers.

See SUMF ¶ 47 [Ex. 7 at A-149-50 ¶ 21].

According to Dr. Leiva, Rand and Mabury (2011) extracted PFCAs from HDPE bottles treated with differing levels of fluorination by Fluoro-Seal, later named Inhance. They found that the total concentration of PFCAs in fluorinated bottles increased with the level of fluorination and was significantly higher than the levels in unfluorinated bottles. Rand and Mabury then performed a one-year leaching experiment using water showing that these PFCAs migrate into solvents held in the bottles. After one year, the total concentration of PFCAs in water held in fluorinated HDPE bottles (Level 3), exceeded the total concentration of PFCAs in methanol extracts from bottles treated with all levels of fluorination. *See* SUMF ¶ 47 [Ex. 7 at A-140-50 ¶ 6].

On March 5, 2021, EPA issued a press release announcing the results of testing “confirm[ing] that it has detected eight different PFAS from the fluorinated HDPE containers, with levels ranging from 20-50 parts per billion.” *See* SUMF ¶ 57 [Ex. 23, Per- and Polyfluoroalkyl Substances (PFAS) in Pesticide and Other Packaging at A-706]. According to the

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EPA report presenting these test results, “information given to us by a company that performs fluorination on plastic containers [indicates] that during the fluorination process, HDPE containers are subjected to fluorine elemental gas at pre-determined concentrations and under elevated temperatures. The anticipated chemical reaction results in formation of partially fluorinated long chain polymers and possibly fully fluorinated short chain polymers.” [Ex. 51, EPA’s Analytical Chemistry Branch PFAS Testing Rinses from Selected Fluorinated and Non-Fluorinated HDPE Containers A-1218-19].

On September 8, 2022, EPA announced the results of a follow-up study concluding that “water or methanol used as surrogates for pesticide formulations (or other solutions similar to water or methanol) stored in fluorinated containers had quantifiable PFAS levels, which indicated that PFAS from container walls leached into the contents of the container.” *See* SUMF ¶ 67 [Ex. 30, EPA Releases Data on Leaching of PFAS in Fluorinated Packaging at A-770-76]. The agency positively identified eight compounds in the leachate from fluorinated bottles, five of which were LCPFACs, including PFOA. Moreover, EPA found that with increasing residence time, the sum concentration of PFAS in both solvents increased, indicating that PFAS continued to leach from the containers over time. *See* SUMF ¶ 67 [Ex. 7 at A-144 ¶ 12].

Vitale et al. (2022) conducted a series of leaching experiments using fluorinated and non-fluorinated HDPE bottles. At every interval during the 12-week study period, PFCAs, including PFOA, were detected in the methanol leachate. The most frequently detected PFCAs were those in the C5-C7 chain length. Consistent with the EPA results, the sum concentration of PFAS increased in the leachate with longer residence periods. *See* SUMF ¶ 41 [Ex. 7 at A-145-46 ¶ 14].

Most recently, Whitehead and Peaslee (2023), provided evidence of leaching of PFCAs from directly fluorinated HDPE containers into different solvents and foodstuffs. Whitehead and

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Peaslee found that the sum of PFAS concentrations in fluorinated containers was greater than 200 times the concentrations in non-fluorinated containers. Testing identified nine LCPFACs, including PFOA and PFNA, and four short-chain carboxylic acids, including PFBA and PFPeA. According to Dr. Leiva, “[t]hese data confirm that plastic containers subjected to direct, post-mold fluorination, contain high concentrations of PFAS chemicals.” *See* SUMF ¶ 42 [Ex. 7 at A-146 ¶ 16]. The authors also conducted numerous leaching experiments to determine whether these compounds migrated from the containers into solvents and foodstuffs. After a seven-day leaching experiment, they found that water, acetone, and methanol contained PFCAs, with the highest concentration found in methanol, confirming the results of the EPA (2022) studies. Finally, the authors conducted a leaching test using common foods that might be stored in fluorinated containers such as olive oil, mayonnaise, and ketchup. After seven days, PFAS were found in each of the three foodstuffs. The PFAS levels increased over time and when container contents were subjected to elevated temperatures. *See* SUMF ¶ 42 [Ex. 7 at A-147 ¶ 17].

More recent testing by Eurofins, a certified commercial testing laboratory, utilizing the same methodology as Whitehead and Peaslee (2023) confirmed their findings. *See* SUMF ¶ 43 [Ex. 7 at A-155-214].

As Dr. Leiva indicates, across the various studies, 13 PFCAs have been found in fluorinated containers and their contents, including 9 LCPFACs subject to EPA’s SNUR and four short chain PFCAs. These substances are identified in Table 1:

SUBJECT TO MOTION TO EXCEED PAGE AND WORD LIMIT**Table 1.** Perfluoroalkyl carboxylic acids (PFCAs) positively identified in extracts from post-mold fluorinated HDPE plastic containers by study. PFCAs ordered by carbon chain length.

PFAS Compound (C-chain length)	Eurofins (2023)	Whitehead and Peaslee (2023)	Vitale et al. (2022)	EPA (2022)	EPA (2021)	Rand and Mabury (2011)
TFA (C2)						X
PFPrA (C3)						X
PFBA (C4)	X	X	X	X	X	X
PFPeA (C5)	X	X	X	X	X	X
PFHxA (C6)	X	X	X	X	X	X
PFHpA (C7)	X	X	X	X	X	X
PFOA (C8)	X	X	X	X	X	X
PFNA (C9)	X	X	X	X	X	X
PFDA (C10)	X	X	X	X	X	X
PFUnDA (C11)	X	X	X	X	X	
PFDoDA (C12)		X	X			
PFTriDA (C13)		X	X			
PFTDA (C14)		X	X			
PFHxDA (C16)		X				
PFODA (C18)		X				

See SUMF ¶ 36 [Ex. 7 at A-152].

Inhance testing included in the SNUNs also confirms the presence of the nine LCPFACs in fluorinated containers and their contents.⁴ In one notable example, testing conducted by Inhance measured concentrations of LCPFACs in small engine fluorinated fuel tanks and the fuels they contain. In addition to finding high LCPFAC levels in tank materials, Inhance measured substantial concentrations of LCPFAC leaching into the fuel

⁴ The Government has included these testing results in the Appendix to its motion for partial summary judgment. See SUMF ¶ 119 [Ex. 8 at A-56, 58-59; Ex. 9 at A-82, 87-88; Ex. 10 at A-106, A108-109; Ex. 11 at A-126, 128-29; Ex. 12 at A-139, 141-42; Ex. 13 at A-153, 156-57, 162-63; Ex. 14 at A-168, A-173-76; Ex. 15 at A-187, A-189-9]. Because of questions about the test procedures employed and the representativeness of the tested containers of currently available containers in the marketplace, intervenor-plaintiffs do not broadly rely on the Inhance data but cite it primarily as evidence that the formation of PFAS during fluorination is undisputed and confirmed by defendant's own testing.

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itself. Thus, for tanks receiving high levels of fluorination, combined LCPFAC levels in fuel totaled 138 ug/L (ppb), as shown below:

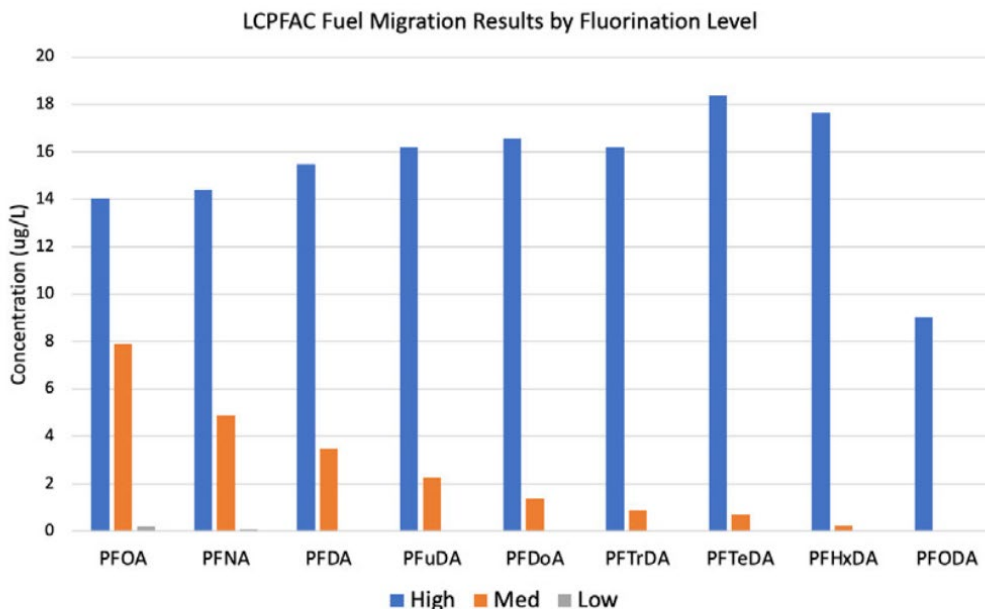


Figure 4. LCPFAC fuel concentrations by fluorination level from land-based small combustion engine fuel tanks

See SUMF ¶ 48 [Ex. 13, SNUN Attachment 003 at A-404]. These levels are substantially higher than LCPFAC levels measured by Peaslee and Whitehead due to leaching from containers.

C. Inhance’s Manufacture and Processing of LCPFACs is a Significant New Use Subject to the SNUR

Because the Inhance fluorination process produces LCPFACs, Inhance “manufactures” these substances as defined in 40 C.F.R. § 720.3(q). It also “processes” LCPFACs as defined in 40 C.F.R. § 720.3(aa) by preparing them for distribution in commerce as part of fluorinated plastic articles that are shipped to users and distributors.

The LCPFAC SNUR defines a “significant new use” of LCPFACs as any “[m]anufacture (including import) or processing for any use after December 31, 2015.” 40 C.F.R. § 721.10536(b)(4)(ii). Although this broad definition plainly applies to LCPFACs

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formed during fluorination, Inhance has claimed that that they are not subject to the SNUR. These claims are foreclosed by the clear language of the SNUR.

First, Inhance claims that, because it was fluorinating containers before the SNUR was proposed on January 21, 2015,⁵ its activities cannot be considered a “significant new use” under section 5(a)(2). However, while the SNUR exempts several uses of LCPFACs that existed prior to January 21, 2015, at 40 C.F.R. § 721.9582(c)(5), fluorination is not among them. To identify LCPFAC uses that were ongoing as of the proposal date, EPA conducted extensive outreach to industry. Thus, the initial 2015 SNUR proposal, 80 Fed. Reg. 2885 (Jan. 21, 2015), and March 3, 2020, reproposal, 85 Fed. Reg. 12479, urged industry to identify existing uses of LCPFACs predating January 21, 2015. However, after learning of several such uses and exempting them from the final rule, EPA expressly declined to establish a general “safe harbor” for pre-2015 uses that were *not* disclosed during the LCPFAC rulemaking. As EPA explained, it “does not believe there should be a safe-harbor provision for uses not identified as ongoing uses in the SNUR . . . since notice of the requirements of this action were provided five years ago.” 85 Fed. Reg. 45109, 45120.

Despite ample opportunity to do so, Inhance failed to inform EPA during the LCPFAC rulemaking that it had produced LCPFACs during fluorination of plastic containers before January 2015 and was continuing to do so.⁶ As a result, the final rule contains no exemption for

⁵ As EPA explained in 1990, “the intent of TSCA section 5(a)(1)(B) is best served by designating a use as a significant new use as of the date of publication of the proposed rule rather than as of the effective date of the final rule.” 55 Fed. Reg. 17376 (Apr. 24, 1990).

⁶ In the Reply in support of its motion to dismiss the Government’s Complaint, Inhance has claimed that it was unaware of the formation of LCPFACs during fluorination until after the SNUR was promulgated in 2020. ECF 27 at 7. However, the 2011 Rand and Mabury study indicates that the fluorinated containers tested were obtained from Fluoro-Seal International, later renamed Inhance. Moreover, any technically savvy company whose business was based on fluorine chemistry would have been intimately familiar with the highly publicized PFAS issue well before the promulgation of the final SNUR in 2020 and could

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Inhance’s activities and there is no mechanism in the rule for granting such an exemption after-the-fact. Inhance has described the amounts of LCPFACs formed during fluorination as “small,” but this too is not a justification for its failure to comply with the SNUR. In its final rule, EPA denied requests to establish an exemption for *de minimis* levels of LCPFACs. *Id.* at 45120. Moreover, as described in Part V, below, the LCPFACs found in fluorinated containers have harmful effects even at very low concentrations and these health concerns amply justify submission of SNUNs so that EPA can carefully assess and mitigate their public health impacts.

Finally, Inhance’s repeated assertions that the LCPFACs found in fluorinated containers are produced “unintentionally” do not exempt them from the SNUR. EPA TSCA regulations state that the term “manufacture for commercial purposes” encompasses “substances that are produced coincidentally during the manufacture, processing, use, or disposal of another substance or mixture.” 40 C.F.R. § 720.3(r). Such substances include “byproducts,” which are “produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance or mixture.” 40 C.F.R. § 720.3(d). LCPFACs formed unintentionally during fluorination qualify as “byproducts” and are subject to SNUR requirements under 40 C.F.R. § 721.45(e). In its March 16, 2022, open letter to industry, EPA advised that companies are obligated by the LCPFAC SNUR “to ensure unintentional PFAS contamination does not occur.” It explained that long-chain PFAS “that are found to be present in or on fluorinated polyolefins . . . would be considered byproducts” that “do not have a

easily have concluded that the reaction between the carboxylic acids in PDPE plastic and free fluorine would result in PFAS formation. Inhance applied for a patent in 2019 for a fluorinated treatment process that demonstrated a high level of awareness of the formation of PFOA and the health concerns associated with it, *See* SUMF ¶ 29 [Ex. 29, United States Patent for Systems and Methods for Processing Fluoropolymer Materials and Related Workpieces at A-794].

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separate commercial intent” and, as such, their formation during “the fluorination of polyolefins [would] be a significant new use under TSCA.” *See* SUMF ¶ 63 [Ex. 23, Per- and Polyfluoroalkyl Substances (PFAS) in Pesticide and Other Packaging at A-743].

D. Inhance’s Continuing Manufacture and Processing of LCPFACs While the SNUNs are Under Review Violate TSCA SNUR Requirements and TSCA Itself

After manufacturing and processing LCPFACs without interruption since the SNUR took effect on September 25, 2020, 85 Fed. Reg. 45109, Inhance finally filed SNUNs for the nine LCPFACs identified in testing of fluorinated containers and their contents at the end of 2022. However, Inhance remains in violation of the SNUR because it continues to manufacture and process the nine LCPFACs *before* EPA has completed its review of the SNUNs, made unreasonable risk determinations, and developed orders under section 5(e) or 5(f) addressing any unreasonable risks. Inhance’s conduct defeats the core purpose of SNUNs under TSCA – to afford EPA an opportunity to assess and restrict potentially hazardous chemicals *before* people and the environment are exposed to their harmful effects.

Section 15 of TSCA, 15 U.S.C. § 2614, provides that it is unlawful for any person to “fail or refuse to comply with any requirement of this title or any rule promulgated . . . under this title.” Manufacture and processing of substances subject to a SNUR without complying with TSCA’s SNUR requirements violate both section 5(a)(1)(A)(ii) and a rule promulgated under section 5(a)(2) and are therefore “prohibited acts” under section 15.

E. Inhance Is Violating the SNUR by Distributing Fluorinated Containers in Commerce Without Notifying Recipients That Their Actions Do Not Comply with the SNUR

Like all SNURs, the LCPFAC SNUR is subject to the general SNUR provisions in 40 C.F.R. § 721, Subpart A. These provisions impose a responsibility on manufacturers of SNUR substances to assure that the customers to whom they are distributed are not engaged in activities

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that violate the SNUR. Thus, 40 C.F.R. § 721.5(d)(1) requires manufacturers to stop supplying the SNUR substance to a downstream user who is in violation of the SNUR:

If at any time after commencing distribution in commerce of a [SNUR] chemical substance . . . a [manufacturer or processor of the substance] . . . has knowledge that a recipient of the substance is engaging in a significant new use of that substance . . . without submitting a notice under this part, the person is required to cease supplying the chemical substance to that recipient . . .

The only exception to this requirement is where the manufacturer or processor “has notified the recipient . . . that the recipient is engaging in a significant new use without submitting a significant new use notice,” and has received “a statement of assurance that the recipient . . . will not engage in the significant new use,” and has provided a copy of this statement to EPA. 40 C.F.R. § 721.5(d)(1)(i).

The SNUR prohibits “processing” as well as “manufacture” of LPCFACs. By receiving unlawfully produced LCPFACs in fluorinated containers from Inhance, filling these containers with products and supplying them to distributors and end-users, Inhance customers are “processors” under TSCA because they are “prepar[ing] LCPFACs after [their] manufacture, for distribution in commerce . . . as part of a mixture or article.” 40 C.F.R. § 720.3(aa)

Inhance knew or should have known that its customers and other container recipients were “processing” LCPFACs and thereby “engaging in a significant new use” no later than March 1, 2022, when EPA informed the company that it was producing LCPFACs in violation of the SNUR. Gov. Compl. ¶ 45. At that point, 40 C.F.R. § 721.5(d)(1) obligated Inhance to cease supplying fluorinated containers to its customers or notify them of the SNUR requirements and obtain written assurance of their compliance and provide it to EPA. It did neither.

Inhance’s failure to take these actions was and is a separate violation of the LCPFAC SNUR and 40 C.F.R. Part 721 and therefore comprises a “prohibited act” under section 15.

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III. INJUNCTIVE RELIEF TO RESTRAIN THE VIOLATIONS IS THE SOLE MEANS TO ENSURE COMPLIANCE WITH TSCA AND MUST BE IMPOSED WITHOUT ANY BALANCING OF THE EQUITIES

If this Court finds Inhance liable for the claimed TSCA violations, it should order injunctive relief to restrain these violations. Injunctive relief is the appropriate remedy in this case under both the TSCA section 20 citizen suit provision invoked by intervenor-plaintiffs and the section 17 enforcement provision relied on by the Government.

This injunction should direct Inhance to stop producing and processing LCPFACs during the fluorination of plastic containers, and distributing these containers in commerce until and unless EPA completes its review of the Inhance's SNUNs, makes determinations of unreasonable risk and imposes additional restrictions warranted by these determinations. The injunction should also order Inhance to cease supplying fluorinated containers to its customers or notify them of the SNUR requirements and obtain written assurance of their compliance and provide it to EPA.

As intervenor-plaintiffs show below, given the nature of Inhance's violations and the enforcement remedies authorized in sections 17 and 20 of TSCA, an injunction restraining these violations is required without consideration of the usual factors for equitable relief, including a showing of irreparable harm, consideration of the public interest, and balancing the equities. However, even if those factors are considered, they also command the imposition of the requested injunctive relief, given TSCA's public interest purposes to protect human health and the environment, the irreparable harm caused by defendant's ongoing violations, and the knowing and willful nature of those violations, which disqualify Inhance from claiming that the equities weigh in its favor. *See* Parts IV and V below.

A. Courts Must Impose Injunctive Relief Where It is the Only Means of Enforcing Compliance with an Unequivocal Statutory Command

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While a court has equitable discretion to refrain from issuing injunctive relief under some circumstances, this is not the case where an injunction is the only means to ensure compliance with a statute. The Supreme Court addressed the role of equitable discretion in environmental enforcement suits in *Weinberger v. Romero-Barcelo*, 456 U.S. 305 (1982). This was a citizen suit under the Federal Water Pollution Control Act (“FWPCA”) (also known as the Clean Water Act or CWA) against the Navy for the accidental discharge of ordnance into the sea during training exercises without a permit. The Court stated, “An injunction is a matter of equitable discretion; it does not follow from success on the merits as a matter of course,” 456 U.S. at 311-12, and held that the District Court acted within its discretionary authority in limiting the relief to ordering the Navy to apply for a permit. *Id.* at 320.

However, the Court made clear that an injunction was not required ONLY because, unlike here, it was “not the only means of ensuring compliance,” and that courts should order relief “necessary to secure prompt compliance with the Act.” *Id.*, *see also Amoco Prod. Co. v. Vill. of Gambell*, 480 U.S. 531, 543 (1987) (the basis for the holding in *Romero-Barcelo* was that “an injunction against all discharges was not the only means of ensuring compliance with the Act”). The Court in *Romero-Barcelo* concluded that its decision that an immediate injunction against the discharges was not required was dependent on the likelihood that a permit approving the discharges would issue. *Id.* at 329. If that were not the case, the Court would need to reconsider its ruling. *Id.*

In a later case, the Supreme Court explicitly confirmed that courts only have the discretion to decline to impose an injunction to remedy a statutory violation when there are other mechanisms to achieve compliance. *United States v. Oakland Cannabis Buyers’ Coop.*, 532 U.S. 483 (2001). The Court explained that

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[courts’] choice (unless there is statutory language to the contrary) is simply whether a particular means of enforcing the statute should be chosen over another permissible means; their choice is not whether enforcement is preferable to no enforcement at all. Consequently, when a court of equity exercises its discretion, it may not consider the advantages and disadvantages of nonenforcement of the statute, but only the advantages and disadvantages of “employing the extraordinary remedy of injunction,” *Romero-Barcelo*, 456 U.S. at 311, over the other available methods of enforcement.

Id. at 497-98 (footnote omitted); *see also Antoninetti v. Chipotle Mexican Grill*, 643 F.3d 1165, 1175 (9th Cir. 2010) (where there are statutory violations and “an injunction is the only relief available to a private party under the Act, it would be an abuse of discretion for the district court now to deny injunctive relief”); *Ctr. for Biological Diversity v. Pirie*, 201 F. Supp. 2d 113, 115 (D.D.C. 2002), *vacated as moot sub nom, Ctr. for Biological Diversity v. England*, 2003 U.S. App. LEXIS 1110 (D.C. Cir. Jan. 23, 2003) (unpublished) (per curiam) (under the Migratory Bird Treaty Act, the court’s equitable discretion is limited to choosing among appropriate means to ensure compliance with the statute; court may not allow continued violation with impunity).

The Third Circuit has held that an injunction may not issue under the CWA absent a showing of irreparable injury and the inadequacy of legal remedies, relying on *Romero-Barcelo*. *NRDC v. Texaco Ref. & Mktg*, 2 F.3d 493, 506 (3d Cir. 1993); *NRDC v. Tex. Ref. and Mktg*, 906 F2d. 934 (3d Cir. 1990). However, not only did these cases involve the CWA, which provides remedies other than an injunction, but they preceded the Supreme Court’s clear direction in *Oakland Cannabis Buyers* that a court’s remedial discretion does not include non-enforcement in the face of a statutory violation, but only encompasses discretion to choose among available means to achieve compliance.

While some post-*Oakland Cannabis Buyers* cases in other circuits have declined to issue injunctions under citizen suit provisions, there were other mechanisms for enforcement in these cases. Thus, in *Liebhart v. SPX Corp.*, 998 F.3d 772, 774-75, 780 (7th Cir. 2021), state remediation plans were sufficient to remedy the violation. *See also LAJIM, LLC v. GE*, 917 F.3d

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933, 942 (7th Cir. 2019) (plaintiff failed to show that injunctive relief would improve the environment beyond what the state agency had already ordered).

In addition, the *Romero-Barcelo* decision recognized that there are situations where Congressional direction in a statute mandates injunctive relief. As an example, it cited *TVA v. Hill*, 437 U.S. 153 (1978), where the Supreme Court ruled that a violation of the Endangered Species Act (“ESA”) mandated injunctive relief and that Congress had foreclosed the exercise of the usual discretion possessed by the courts. Because the ESA contained a “flat ban” on the destruction of the critical habitats of endangered species, and the challenged action would have destroyed such habitat, only an injunction against the action could vindicate the objectives of the Act. *Romero-Barcelo*, 456 U.S. at 313-14. The Court in *Hill* found that although ordinarily a judge is not “mechanically obligated to grant an injunction for every violation of law,” 437 U.S. at 193, Congress had spoken clearly in the ESA on its priorities, and the Court was required to implement its direction by enjoining the action. *Id.* at 194-95.

B. The Only Meaningful Remedy for the Statutory Violation in this Case is an Injunction Restraining Inhance from Continuing Its Unlawful Conduct

As Congress made clear when it enacted TSCA’s SNUR provisions, “[t]he most effective and efficient time to prevent unreasonable risks to public health or the environment is prior to first manufacture.” S. Rep. 94-698, at 5 (1976), *as reprinted in* 1976 U.S.C.C.A.N. 4491, 4495. To implement this policy, section 5(a)(1) expressly prohibits manufacture and processing of chemicals subject to a SNUR without complying with SNUR requirements. No mitigating factors warranting exemptions to this strict prohibition are identified. As noted in the Senate Report on the original Act, 1976 U.S.C.C.A.N. at 4500, “[t]he [Section 5] notification provisions of the committee bill form[] the backbone of the preventive aspects of health protection sought by this legislation.” Moreover, the 2016 TSCA amendments greatly strengthened this

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precautionary approach by requiring an express determination that the chemical is not likely to present an unreasonable risk before allowing the significant new use to proceed, and by directing that determinations of unreasonable risk must be made “without consideration of costs or other nonrisk factors.” 15 U.S.C. § 2604(e)(1)(A)(ii)(I), (f)(1).

Thus, as in *Hill*, TSCA imposes a “flat ban” on significant new uses of chemicals subject to SNURs until all the steps in the SNUR review process have been completed. Since Congress has decided that discretionary considerations should play no role in imposing this ban, the courts may not consider such factors in determining whether to enjoin unlawful manufacture of substances in violation of a SNUR. Accordingly, such an injunction is the only judicial relief that would achieve compliance with TSCA and is the path that must be followed by this Court.

C. TSCA’s Enforcement Authorities are Aimed at Providing Injunctive Relief Restraining Violations

The remedies Congress made available to the Court under TSCA’s enforcement authorities are likewise focused on compelling compliance with obligations imposed by the statute and EPA regulations.

The citizen suit provision, section 20(a) of TSCA, provides that “any person may commence a civil action . . . to restrain [a] violation” of TSCA or its implementing regulations.

15 U.S.C. § 2619(a)(1).⁷ No other remedy is identified.⁸ The courts have interpreted TSCA

⁷ Intervenor-plaintiffs’ Complaint in this Court cites the section 20 citizens’ suit provisions as a basis for the injunctive relief intervenors request. Int. Com. (ECF 36) ¶¶ 6, 35-39. Intervenor-plaintiffs believe that since section 20(b) provides an unconditional right of intervention in enforcement actions filed by the Government, it carries with it the ability to seek the enforcement remedies authorized in section 20(a).

⁸ In this respect, section 20(a) differs markedly from the citizen suit provisions of some other environmental laws, which authorize other relief such as civil penalties. *See e.g.*, 33 U.S.C. § 1365 (citizen suit provision under the Clean Water Act includes civil penalties as a remedy that may be ordered by the district court); 42 U.S.C. § 7604 (same under the Clean Air Act); 42 U.S.C. § 6972(a) (same for Solid Waste Disposal Act). Here, Congress did not provide any other remedy that could command compliance with the statute.

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section 20 to mean that the appropriate and only remedy in a successful citizen's suit is injunctive relief to restrain ongoing violations. *See e.g., Good v. Am. Water Works Co.*, 2016 U.S. Dist. LEXIS 141219, *39 (S.D.W.V. 2016); *Arbor Hill Concerned Citizens Neighborhood Ass'n v. City of Albany*, 250 F. Supp. 2d 48, 60 (N.D.N.Y. 2003); *USS Cabot/Deballo Museum Found. v. United States Customs Serv.*, 1995 U.S. Dist. LEXIS 4068, *2 (E.D. La. Mar. 29, 1995); *see also Puerto Rico v. Shell Oil Co. (In re Methyl Tertiary Butyl Ether (MBTE) Prods. Liab. Litig.)*, 117 F. Supp. 3d 276, 295 (S.D.N.Y. 2015) (TSCA citizen suit plaintiffs are "limited to injunctive relief for ongoing violations").

Likewise, TSCA section 17, 15 U.S.C. § 2616, provides that the district courts have jurisdiction over Government civil actions to restrain violations and prohibited conduct and to compel actions required by the Act. 15 U.S.C. § 2616(a)(1)(A)-(C). It also provides that the court may direct manufacturers or processors in violation of TSCA to give notice of the violation to distributors and others in possession of the chemical, give public notice of the risk of injury, and replace or repurchase violative products. 15 U.S.C. § 2616(a)(1)(D).⁹ Thus, like section 20(a), section 17 directs the Court to impose injunctive relief to restrain violations of SNUR requirements and does not authorize alternative forms of relief.

In sum, in this case, not only is there no other form of relief provided in the enforcement provisions of the statute, but as a practical matter there is no means other than an injunction to ensure compliance with TSCA. Thus, Congress has balanced the equities in its legislation, determining that the public interest lies in enjoining significant new uses of chemicals until they

⁹ Ordering solely notification and replacement of products alone, without enjoining the continuing violation, would make no sense, as it would be allowing continued distribution in commerce only to then require a continuous recall of those products. Thus, we must assume that this additional form of relief is intended to supplement the main relief of enjoining the violations.

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are reviewed for unreasonable risk and regulated by EPA. Accordingly, the Court has no choice but to enjoin Inhance's ongoing violations of the LCPFAC SNUR. *TVA*, 437 U.S. at 193-94 (court may not balance equities and hardships when Congress has dictated the priorities); *United States v. Bethlehem Steel Corp.*, 38 F.3d 862, 868 (7th Cir. 1994) (injunctive relief proper without balancing equities because the case involved disposal of hazardous waste, which the governing statute found could present a danger to human health and the environment).

IV. INHANCE'S KNOWING AND WILLFUL NON-COMPLIANCE WITH TSCA STRONGLY WEIGHS AGAINST ANY BALANCING OF EQUITIES

Yet another reason that the Court need not balance any equities in considering the need for injunctive relief is that Inhance's ongoing violations of TSCA are knowing and willful. It is undisputed that Inhance deliberately chose to manufacture LCPFACs in blatant disregard of SNUR requirements even after being informed by EPA that it was in violation of TSCA and needed to stop LCPFAC manufacture until fully complying with the SNUR.

Where a statutory violation is willful, an injunction should issue without a need to balance the equities. *Bethlehem Steel*, 38 F.3d at 867-68 ("it is an accepted equitable principle that a court does not have to balance the equities in a case where the defendant's conduct has been willful") (quoting *EPA v. Environmental Waste Control, Inc.*, 917 F.2d 327, 332 (7th Cir. 1990)) (citing *Guam Scottish Rite Bodies v. Flores*, 486 F.2d 748, 749 (9th Cir. 1973)); *United States v. Marine Shale Processors*, 81 F.3d 1329, 1358-59 (5th Cir. 1996) (the court is relieved of its normal obligation to balance the equities where a defendant has willfully and repeatedly violated the environmental laws); *accord, Or. State Pub. Interest Research Grp. v. Pac. Coast Seafoods Co.*, 374 F. Supp. 2d 902, 908 (D. Or. 2005).

The Government's Complaint recounts in exhaustive detail EPA's failed two-year struggle to persuade Inhance to stop producing LCPFACs during fluorination and comply with

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the SNUR. In early September 2020, shortly before the SNUR took effect, EPA became aware of the PFAS contamination data developed by PEER for the Anvil 10+10[®] mosquito control pesticide. Govt Com at ¶ 33. In December 2020, EPA received unused fluorinated HDPE containers from the distributor of Anvil 10+10[®] and, through its own testing, detected several PFAS subject to the SNUR in the rinsates (a solvent used to extract chemical compounds). *Id.* ¶¶ 34-35. On January 14, 2021, EPA issued a lengthy press release “making new information available about EPA testing that shows PFAS contamination from fluorinated containers.” *See* SUMF ¶ 52 [Ex. 22, EPA Takes Action to Investigate PFAS Contamination at A-698]. The Agency emphasized that it “considers any level of PFAS to be potentially toxicologically significant.” *See* SUMF ¶ 52 [Ex. 22, EPA Takes Action to Investigate PFAS Contamination at A-701].

On the same day, EPA issued a subpoena under Section 11(c) of TSCA, 15 U.S.C. § 2610(c) seeking information concerning Inhance’s fluorination processes. Govt Com, ¶ 37. Based on Inhance’s response, “EPA determined that Inhance’s processes for fluorinating containers results in the manufacturing for a significant new use of PFAS subject to the Long-Chain PFAS Rule because PFAS are produced as byproducts of the fluorination process.” *Id.* ¶ 39.

Despite the EPA and PEER testing and the subpoena, Inhance maintained that “we have been, and continue to be, in full compliance with all relevant regulations and regulatory guidance, and are operating safely, responsibly and lawfully.” *See* SUMF ¶ 58 [Ex. 25, Inhance Technologies Statement on Regulatory Compliance at A-724]. At a meeting with EPA on September 8, 2021, Inhance dismissed the results of the Agency’s testing by claiming that nearly all the PFAS found in the Anvil 10+10 pesticide were “not attributable to fluorinated barrier

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packaging” and that, “under actual conditions of use, PFAS levels attributable to Anvil 10+10 in fluorinated packaging will be insignificant, and likely unmeasurable.” *See* SUMF ¶ 59 [Ex. 26, Inhance Presentation to EPA at A-735, 738].

However, EPA did not agree with Inhance’s claims and, on March 1, 2022, issued a Notice of Violation (“NOV”) informing the company that its process for fluorinating HDPE containers produced PFAS subject to the SNUR and that Inhance’s manufacturing or processing of such PFAS was a violation of TSCA. Govt Com, ¶ 40. The NOV requested any information on any changes Inhance may have made to its fluorination process eliminated the manufacture of PFAS subject to the LCPFAC SNUR. *Id.* ¶ 41. The NOV further stated that “if Inhance had not changed its process for fluorinating HDPE containers to prevent the manufacture of long-chain PFAS substances, Inhance must immediately cease the manufacture of PFAS subject to the Long-Chain PFAS Rule and may not resume manufacture until it has submitted a New Use Notice and the EPA issues a determination on that New Use Notice.” *Id.* ¶ 42.

Two weeks later, on March 16, 2022, EPA published an open letter to industry stating that it had “determined via testing that certain per- and polyfluoroalkyl substances (PFAS) have formed and migrated from these fluorinated polyolefins.” *See* SUMF ¶ 63 [Ex. 27 at A-742]. As a result, “[t]he agency is notifying companies of their obligation to comply with existing requirements under the [TSCA] to ensure unintentional PFAS contamination does not occur.” It explained that “long-chain PFAS as defined in EPA’s 2020 long-chain perfluoroalkyl carboxylate (LCPFAC) [SNUR] that are found to be present in or on fluorinated polyolefins may be subject to TSCA regulations and enforcement” because “their formation during “the fluorination of polyolefins [would] be a significant new use under TSCA.” *Id.* at A-743. After SNUNs are filed for PFAS subject to the SNUR, EPA advised, “[e]ntities may not commence manufacturing

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(including import) or processing for the significant new use until EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination.” *Id.*

In the wake of EPA’s March 2022 NOV and open letter to industry, Inhance could have followed EPA’s guidance by halting production of PFAS during fluorination and submitting SNUNs for LCPFACs subject to the SNUR. Yet on March 21, 2022, Inhance issued a press release stating that it “is pleased to announce that its Enkase barrier technology does not impart long-chain perfluoroalkyl carboxylate (LCPFAC) chemical substances to high-density polyethylene (HDPE) packaging.” *See* SUMF ¶ 64 [Ex. 28, Inhance Technologies Announces its Enkase Technology Does not Impart LCPFACs to HDPE Packaging at A-745]. Inhance cited testing (which it did not release to the public) purportedly documenting the absence of LCPFACs but did not mention EPA’s own testing showing the exact opposite or the NOV it had received from EPA three weeks earlier.

Between April and August 2022, EPA reviewed additional information submitted by Inhance in response to the NOV and again determined that Inhance’s fluorination of fuel tanks and containers entailed the manufacture of LCPFACs subject to the SNUR. Govt Com ¶ 40. On September 8, 2022, EPA announced release of a report of a new round of testing on fluorinated containers which found that “[w]ater or methanol used as surrogates for pesticide formulations (or other solutions similar to water or methanol) stored in fluorinated containers had quantifiable PFAS levels, which indicated that PFAS from container walls leached into the contents of the container.” *See* SUMF ¶ 67 [Ex. 30 at A-771]. Based on these results, EPA “determined that liquid products packaged in HDPE containers treated with fluorination technology could leach certain PFAS into products from the container walls, even with water-based products. In

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addition, the total amount of PFAS leached into the products could increase over storage time and cause undisclosed levels of PFAS in a pesticide (or other) product.” *Id.*

Again emphasizing that “EPA considers any level of PFAS to be potentially toxicologically significant,” the September 8, 2022 announcement reiterated that “the manufacturing of certain PFAS from the fluorination of polyolefins [is] subject” to the LCPFAC SNUR under TSCA, which “requires industry to notify EPA at least 90 days before starting manufacturing or processing . . . so that EPA could review any associated risks and impose any needed protections.” *See* SUMF ¶ 68 [Ex. 30 at A-772]. It underscored that the “failure to submit such a notification would be a violation of TSCA” and that “[i]f companies find PFAS in their products, they should notify EPA and take action to remove contaminated products.” *Id.*

On September 7, 2022, the day before EPA’s announcement, Inhance informed the Agency that it intended to submit SNUNs for LCPFACs subject to the SNUR but would continue to produce these substances. Govt Com ¶ 45. In a Webinar on sustainable packaging technology the same month, Inhance flatly stated that its “Enkase barrier technology does not impart long-chain perfluoroalkyl carboxylate (LCPFAC) chemical substances to HPDE, as confirmed by independent testing” and that it was “not sure where EPA thinks it’s seeing perfluorinated species but it’s not from Inhance.” *See* SUMF ¶ 70 [Ex. 31, Inhance Webinar at A-779]. Yet as discussed above on page 13, the SNUNs that Inhance would soon submit would acknowledge that the formation of LCPFACs during fluorination was “unavoidable” and testing conducted by Inhance had confirmed their presence.

In short, Inhance had every reason to know that it was in violation of the SNUR and ultimately conceded as much in its SNUNs yet chose to maintain that its fluorinated containers were PFAS-free in the face of contrary evidence. Moreover, EPA repeatedly made it apparent

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that, where LCPFACs were detected in fluorinated containers, TSCA required both the submission of SNUNs AND the cessation of LCPFAC production until the completion of the EPA review process. However, Inhance chose to continue producing PFAS in non-compliance with TSCA while seeking the benefits of filing SNUNs. It is hard to imagine a more knowing and willful violation of the law. The Court should thus give no credence to any countervailing “equities” Inhance may assert and enjoin its undisputed TSCA violations.

V. THE PUBLIC INTEREST IN PREVENTING HARM TO PUBLIC HEALTH STRONGLY FAVORS INJUNCTIVE RELIEF

A. Protection of Public Health Is a Controlling Consideration in Determining Whether to Restrain Violations of Environmental Laws

Even in decisions that employ the traditional four factors to consider the propriety of injunctive relief in statutory violation cases, these factors are applied in light of the public interest purposes of the statute. As the Supreme Court found in *Hecht Co. v. Bowles*, 321 U.S. 321, 331 (1944), in a statutory injunction case, “the standards of the public interest, not the requirements of private litigation measure the propriety and need for injunctive relief.”

Under environmental statutes, harms to public health are considered irreparable and the public interest, as well as the balance of equities, generally favors injunctive relief.¹⁰

“Environmental injury, by its nature, can seldom be adequately remedied by money damages and is often permanent or at least of long duration, *i.e.*, irreparable. If such injury is sufficiently likely, therefore, the balance of harms will usually favor the issuance of an injunction to protect the environment.” *Amoco Prod. Co.*, 480 U.S. at 545; *see also Matter of Commonwealth Oil Ref.*

¹⁰ The fourth factor, that monetary damages are inadequate to compensate for the injury, is met here because, even setting aside whether injury to human health and environment can be adequately compensated by money damages, they are not available in a TSCA citizen or government enforcement suit.

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Co., Inc., 805 F.2d 1175, 1190 (5th Cir. 1986) (“Enforcement of the environmental laws is in the public interest”). Where potential environmental hazards are involved, there is a “congressional thumb on the scale in favor of remediation.” *Me. People's All. v. Mallinckrodt, Inc.*, 471 F.3d 277, 297 (1st Cir. 2006). In such cases, the court’s primary concern is “how best to remedy a potentially serious near-term environmental hazard.” *Id.*

In this context, economic injury to a private party or even the larger public carries little weight when balanced against environmental hazards. For example, in *United States v. Gear Box Z Inc.*, 526 F. Supp. 3d 522, 529 (D. Ariz. 2021), the court found that the enactment of the Clean Air Act (“CAA”) to combat air pollution was “itself is a declaration of public policy. The public interest in halting Defendant's acts that likely violate the CAA outweighs Defendant's interest in continuing to operate a private business.” Likewise, in *League of Wilderness Def. v. Forsgren*, 184 F. Supp. 2d 1058, 1070-71 (D. Or. 2002), the court found that financial hardship to the Forest Service, the intervenor timber company and nearby communities was outweighed by the environmental injury from salvage logging in the absence of an injunction.

In this case, compelling public health considerations favor an order immediately restraining defendant Inhance from producing PFAS during the fluorination of plastic containers. PFAS are universally recognized as a global threat to health and the environment. Thirteen PFAS have been consistently found in fluorinated containers and their contents, including uniquely dangerous LCPFACs and shorter chain PFCAs known to cause multiple harmful effects. Over 200 million containers and other items are fluorinated each year and used to distribute numerous consumer, commercial and industrial products. *See* SUMF ¶ 14 [Ex. 20, Making the Impossible Possible at A-634]. These containers are now exposing a large segment of the US population to PFAS at unsafe levels. If Inhance is allowed to continue to place

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fluorinated containers in the stream of commerce in violation of EPA’s SNUR, the *result will be more PFAS exposure and risk, further endangering public health*. An injunction immediately halting the production of PFAS during fluorination is essential to prevent this harmful result and protect public health.

B. The 14 LCPFACs and Short-Chain PFCAs in Fluorinated Containers Have Serious Health Effects at Low Levels of Exposure

1. The Urgency of Addressing PFAS

EPA has recognized that PFAS “are an urgent public health and environmental issue facing communities across the United States.” *See* SUMF ¶ 76 [Ex. 33, EPA PFAS Road Map at A-790]. As EPA has explained, “[d]ue to their strong carbon-fluorine bonds, many PFAS can be very persistent in the environment with degradation periods of years, decades, or longer under natural conditions.” *See* SUMF ¶ 76 [Ex. 34, EPA PFAS Action Plan at A-825]. PFAS are often called “forever chemicals” and “[d]ue to their widespread use, physicochemical properties, and prolonged persistence, many PFAS co-occur in exposure media (*e.g.*, air, water, ice, sediment), and bioaccumulate in tissues and blood of aquatic as well as terrestrial organisms, including humans.” 88 Fed. Reg. 18638, 18642 (Mar. 29, 2023). PFAS have been detected in the blood of the general U.S. population, with 98 percent of those sampled showing detectable levels of these compounds. 88 Fed. Reg. at 18643. PFAS are associated with “significant and diverse” adverse health effects that “include (but are not limited to): cancer and effects on the liver (*e.g.*, liver cell death), growth and development (*e.g.*, low birth weight), hormone levels, kidney, immune system, lipid levels (*e.g.*, high cholesterol), the nervous system, and reproduction.” *Id.*

2. Rationale for the LCPFAC SNUR

Over two decades ago, industry and EPA identified LCPFACs as PFAS raising serious health and environmental concerns that warranted their elimination from commerce. In the early

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2000s, one member of this class – PFOA – was implicated in large-scale contamination of drinking water near a DuPont facility in West Virginia. Follow-up studies as part of a legal settlement demonstrated links to a host of serious health problems in the exposed population. *See* SUMF ¶ 80 [Ex. 18, PEER CEH SNUN Comment at A-596]. Against this backdrop, in 2006, at EPA’s urging, the principal manufacturers and processors of PFOA and related LCPFACs formed a PFOA Stewardship Program with “a goal of reducing facility emissions and product content of LCPFAC chemical substances on a global basis by 95%, no later than 2010, and to eliminate emissions and product content of these chemical substances by 2015.” 80 Fed. Reg. 2885, 2890.

The LCPFAC SNUR was first proposed in 2015 to coincide with the cessation of LCPFAC production under the Stewardship Program. The proposal was based on EPA’s concern that “the manufacturing or processing of these chemical substances for the proposed significant new uses could be reinitiated in the future . . . [and] would significantly increase the magnitude and duration of exposure to humans and the environment to these chemical substances.” *Id.* As a result of the restrictions imposed by the SNUR, “EPA expect[ed] the presence of LCPFAC substances in humans and the environment to decline over time.” *Id.*

The proposed SNUR focused heavily on PFOA as a representative of the LCPFAC class. As the proposal explains, “PFOA is persistent, widely present in humans and the environment, has a half-life in humans of 2.3–3.8 years, and can cause adverse effects in laboratory animals, including cancer and developmental and systemic toxicity.” 85 Fed. Reg. 45109, 45113. According to EPA, “[h]uman epidemiology data report associations between PFOA exposure and high cholesterol, increased liver enzymes, decreased vaccination response, thyroid disorders, pregnancy-induced hypertension and preeclampsia, and cancer (testicular and kidney).” *Id.*

SUBJECT TO MOTION TO EXCEED PAGE AND WORD LIMIT**3. EPA Proposed Drinking Water Regulations for PFOA and PFNA**

On March 29, 2023, EPA proposed landmark National Primary Drinking Water Regulations (“NPDWRs”) for six PFAS under the Safe Drinking Water Act (“SDWA”). 88 Fed. Reg. 18638. Two of these substances, PFOA and perfluorononanoic acid (“PFNA”), are LCPFACs found in fluorinated containers. EPA’s proposed regulations impose extraordinarily stringent restrictions on the presence of these two LCPFACs in drinking water to protect public health.

Thus, EPA proposed a health-based Maximum Contaminant Level Goal (“MCLG”) for PFOA of zero. As defined by the SDWA, an MCLG is the “maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of persons would occur, allowing an adequate margin of safety.” 40 C.F.R. § 141.2. In setting an MCLG of zero, EPA “determined that PFOA is *Likely to be Carcinogenic to Humans* based on sufficient evidence of carcinogenicity in humans and animals and . . . there is no evidence demonstrating a threshold level of exposure below which there is no appreciable cancer risk (USEPA, 2005)” 88 Fed. Reg. 18638, 18660 (emphasis in original).

Where the MCLG is not achievable, EPA issues a Maximum Contaminant Level (“MCL”) setting the lowest feasible limit on the concentrations of the contaminant allowable in drinking water. For PFOA, EPA proposed an MCL of 4.0 parts per trillion (“ppt”), which EPA determined “is the lowest concentration that PFOA . . . can be reliably quantified.” *Id.* at 18639. By comparison, as Dr. Diaz Leiva notes in her report, PFOA was consistently found in extracts and solvents in fluorinated containers at significantly higher levels ranging from 0.13 parts per billion (“ppb”) to 4.49 ppb, *between 32.5 and 1,122.5 times higher than the proposed MCL.* See SUMF ¶ 37 [Ex. 7 at A-153].

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EPA's proposal also reviews the adverse health effects of PFNA, concluding that "[a]nimal toxicity studies have reported adverse health effects, specifically on development, reproduction, immune function, and the liver, after oral exposure to PFNA." 88 Fed. Reg. 18638, 18646. The report of Dr. Drake Phelps and Professor Jamie DeWitt of East Carolina University highlights the following adverse effects: reproductive and developmental toxicity; immunotoxicity; hepatotoxicity; endocrine disruption; metabolic disorders; neurotoxicity, and cardiovascular toxicity. *See* SUMF ¶ 92 [Ex. 6 at A-56 (footnotes omitted)]. As explained by Drs. Phelps and DeWitt, based on developmental toxicity in rodents, EPA derived a health-based water concentration for PFNA of 0.00001 mg/L or 10 ppt. In the Whitehead and Peaslee study, by contrast, PFNA was measured at concentrations up to 3.61 ng/g in fluorinated HDPE, equivalent to 3.61 ppb or 3,610 ppt. *In one gram of fluorinated HDPE, accordingly, there is more than 360 times the acceptable level of PFNA, according to EPA's calculations. See* SUMF ¶ 94 [Ex. 6 at A-64].

4. Health Effects of Seven Other LCPFACs

In their report, Dr. Phelps and Professor DeWitt also review the literature on the reported health effects of the other 7 LCPFACs found in fluorinated containers. While the available data varies by substance, human and animal studies consistently show that most of these LCPFACs cause reproductive and developmental toxicity, endocrine disruption, immunotoxicity and cardiovascular toxicity. *See* SUMF ¶ 96 [Ex. 6 at A-57-63]. This is consistent with the guiding premise of the SNUR: LCPFACs should be treated as a class of PFAS with a common mode of toxicity and the same health effects as PFOA. Dr. Phelps and Professor DeWitt endorse this as a prudent, health-protective approach. *See* SUMF ¶ 97 [Ex. 6 at A-66].

5. Comparison Between Adverse Health Outcomes from LCPFAC Exposure and Levels in Fluorinated Containers and their Contents

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In the DeWitt/Phelps report, “data from Whitehead and Peaslee were compared to data published in scientific literature reporting statistically significant adverse health outcomes in the human population.” This comparison focused on six LCPFACs for which available human studies reported statistically significant adverse health effects and associated levels of the LCPFAC in human blood (serum): PFOA, PFNA, PFDA, PFUnDA, PFDoDA and PFTrDA. For all six substances and each endpoint, “adverse health outcomes were observed at serum concentrations that overlap with or are exceeded by the range of concentrations reported for . . . fluorinated HDPE by Whitehead and Peaslee.” *See* SUMF ¶ 105 [Ex. 6 at A-55, 57-60].

6. Health Effects of Short-Chain PFCAs Co-occurring in Fluorinated Containers

As described in Dr. Diaz Leiva’s declaration, four short-chain PFCAs were also consistently detected in fluorinated containers: iperfluorobutanoic acid (“PFBA”), perfluoropentanoic acid (“PFPeA”), perfluorohexanoic acid (“PFHxA”) and perfluoroheptanoic acid (“PFHpA”). *See* SUMF ¶ 98 [Ex. 7 at A-152]. As discussed by Dr. DeWitt and Dr. Phelps, these short-chain PFCAs have caused many of the same health effects as LCPFACs. For example, it has been reported that PFBA and PFHxA are as potent as PFOA for hepatotoxicity in rodents. *See* SUMF ¶ 99 [Ex. 6 at A-68]. Drs. DeWitt and Phelps emphasize that, “the presence of these compounds [in fluorinated containers] may also prove problematic in terms of their individual toxicity and their toxicity as part of a PFAS mixture.” *Id.* Thus, a health-protective risk assessment should reflect the combined health effects of the nine LCPFACs and the four short-chain PFCAs.

7. Additive Risks of the 13 PFCAs Produced During Fluorination

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EPA’s proposed drinking water standards for PFOA and other PFAS also demonstrate that an assessment of the health impacts of PFAS levels in fluorinated containers must account for the *additive effects* of all the PFAS formed during fluorination. To account for their combined health effects when they co-occur as a mixture in drinking water, EPA’s drinking water proposal derives combined MCLGs and MCLs for four PFAS, including PFNA. As EPA has explained: “Studies with PFAS and other classes of chemicals support the health protective assumption that a mixture of chemicals with similar observed effects should be assumed to also act in a dose additive manner unless data demonstrate otherwise (USEPA, 2023d).” 88 Fed. Reg. 18638, 18654. Elaborating, EPA said that an assumption of additivity “provides the most health protective endpoint for multiple PFAS in a mixture to ensure there would be no known or anticipated adverse effects on the health of persons [I]f the Agency only established an individual MCLG, the Agency would not provide any protection against dose-additivity from regulated co-occurring PFAS.” *Id.* at 18655.

As Dr. Phelps and Professor DeWitt concluded, a dose-additivity approach is justified for the thirteen PFCAs found in fluorinated containers and their contents because they are similar in chemical structure, exhibit similar adverse effects in human and animal studies, and co-occur during fluorination and the use of fluorinated containers, resulting in simultaneous exposure by workers and consumers who come in contact with these containers. *See* SUMF ¶ 102 [Ex. 6 at A-65-67]. By contrast, comparing toxicity values for each individual PFCA to its levels in containers would greatly understate health risks by failing to consider the additive toxicities of the multiple PFCAs to which container users are exposed. *Id.*

A simple illustration from Drs. DeWitt and Phelps puts in perspective the level of risk from combined exposure to the 13 PFAS formed during fluorination of HPDE containers. Total PFCA

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levels measured in container contents by Whitehead and Peaslee ranged from 0.47 ppb to 94.81 ppb. Using PFOA as a surrogate for all PFAS found in fluorinated HDPE, total PFAS levels exceed the Reference Dose (“RfD”) for PFOA used to derive the proposed MCL *by a factor of 15,000-3,000,000 on a ng/g (ppb) basis.*¹¹ This comparison only considers PFOA’s non-cancer effects. EPA’s proposed drinking water standard sets a MCLG of zero based on PFOA’s carcinogenicity, which would mean that, assuming equivalent carcinogenic potency by the other PFCAs, any level of these substances in fluorinated containers would be unsafe.

While the comparison between PFAS levels in drinking water and fluorinated containers is not exact, it reinforces EPA’s heightened concern about exposure to even minuscule concentrations of LCPFACs and other PFCAs and underscores that the levels of these substances in fluorinated containers significantly exceed concentrations that EPA has deemed unsafe.

C. There Are Many Pathways for Significant Worker and Consumer Exposure Throughout the Life-Cycle of Fluorinated Containers

The magnitude of the health threat from the continued presence of PFAS in fluorinated containers is underscored by the many pathways for human exposure to these containers and their contents. Given the diverse use profile of fluorinated containers, the large volume of containers fluorinated each year, and their widespread distribution in commerce, there are multiple opportunities for worker and consumer exposure throughout the container life-cycle.

1. Extensive Uses of Fluorinated Containers

Inhance fluorinates over 200 million containers and other items each year. *See* SUMF ¶ 14 [Ex. 20 at A-634]. These containers are used for a variety of consumer, commercial and

¹¹ EPA defines RfD as an estimate of daily exposure to the human population (including sensitive populations) that is likely to be without an appreciable risk of deleterious effects during a lifetime.” 88 Fed. Reg. 18638, 18652-3.

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industrial products found in nearly every sector of the economy. Examples cited by Inhance in the SNUNs include household spray cleaners, household countertop polish, floor cleaners and polish, furniture wipes, spray pesticides and herbicides, hose-end sprayer herbicides, commercial pesticides, and industrial chemical storage. *See* SUMF ¶ 18 [Ex. 9, SNUN Attachment Number: 005 at A-217, 257]. In a presentation to the Petroleum Packaging Council (“PPC”) in 2015, Inhance identified these additional applications for fluorinated containers:

Inhance Technologies provide a highly effective barrier against a wide range of contents found in many markets.	
Acids	Hazardous Waste
Adhesives	Hydrogen Bromide
Agricultural Chemicals	Industrial Chemicals
Alcohols	Janitorial Supplies
Bleaching Compounds	Lab Packs
Cleaners	Lubricants
Commercial Chemicals	Medical Waste
Corrosive Chemicals	Paint and Related Products
Detergents	Pastes
Dyes and Pigments	Peroxides
Edible Oils	Personal Care Products
Fire-Fighting Foams	Pharmaceuticals
Flammable Liquids	Photochemicals
Flavors	Poisons
Foodstuffs	Refined Petroleum Products
Fragrances	Sanitation Supplies
Fuels	Solvents
Grease	Water Treatment Chemicals

See SUMF ¶ 19 [Ex. 21, The Benefits of Fluorination for the Petroleum Industry at A-651].

Inhance also “fluorinates fuel tanks and portable fuel storage containers in a number of major markets: handheld and ground-supported outdoor power equipment (e.g., mowers, string trimmers), power sports (e.g., all-terrain vehicles, personal watercraft, 4x4s), marine (e.g., boats), and portable fuel storage containers (e.g., gas cans) As depicted in the SNUNs, these fuel-using products have widespread consumer uses:

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Figure 1. Example fluorinated fuel tanks, fuel storage containers, and associated equipment

See SUMF ¶ 21 [Ex. 13, SNUN Attachment Number: 003 at A-396].

2. Numerous Pathways for Consumer and Worker Exposure to PFCAs at Each Stage of the Fluorinated Container Life-cycle

Once fluorinated, plastic containers are shipped to product manufacturers, who add liquid or solid contents, or to container distributors, who then supply the containers to processors who either use the containers themselves to package products or further distribute them in commerce. Filled containers are supplied to end-use commercial or industry users or placed in retail sale channels for consumer use. During end-use, workers and consumers have direct contact with containers and their contents. After end-use, tens of millions of containers are landfilled or sent to recycling facilities, where they may be melted and converted into pellets or sheets and reintroduced into the resin manufacturing stream. See SUMF ¶ 106 [Ex. 18 at A-584, 620].

The Inhance SNUNs, See SUMF ¶ 106 [Ex. 12, SNUN Attachment Number: 012 at A-258], provide the following overview of typical pathways for exposure and release:

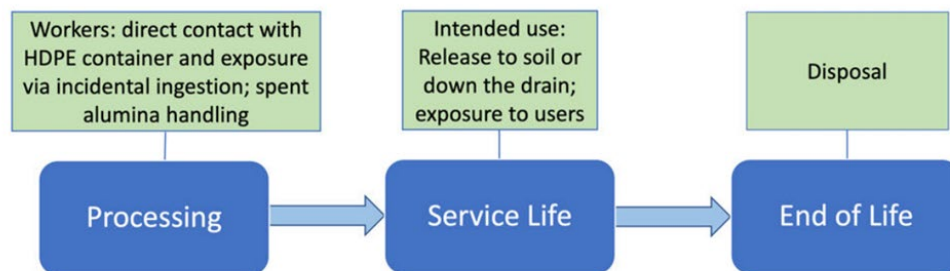
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Figure 1 Conceptual exposure model throughout life cycle

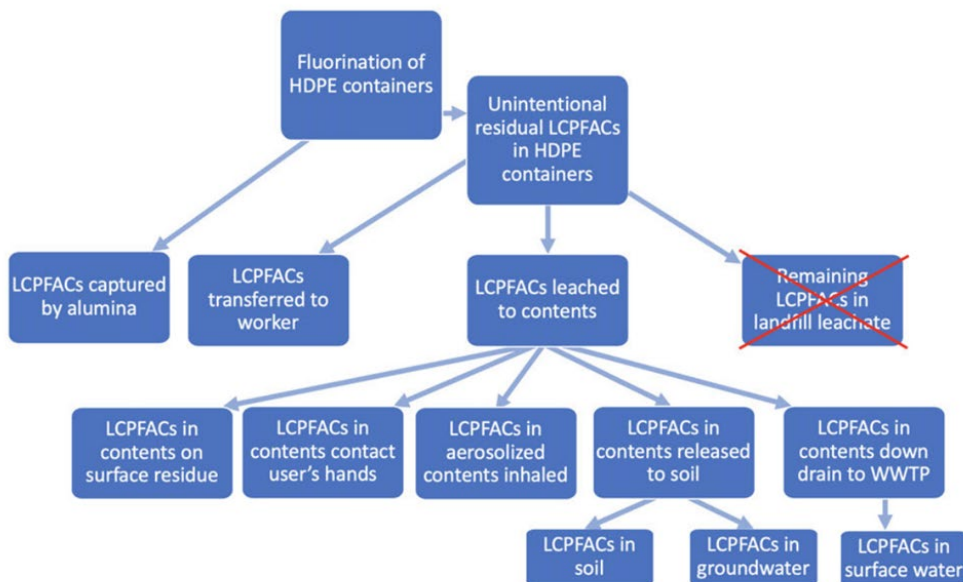


Figure 2 Exposure scenarios modeled by mass balance on HDPE container unit basis

The SNUNs also describe the pathways of exposure of specific fluorinated container applications. An example is fluorinated floor products, SUMF ¶ 107 [Ex. 12, SNUN Attachment Number: 012 at A-286]:

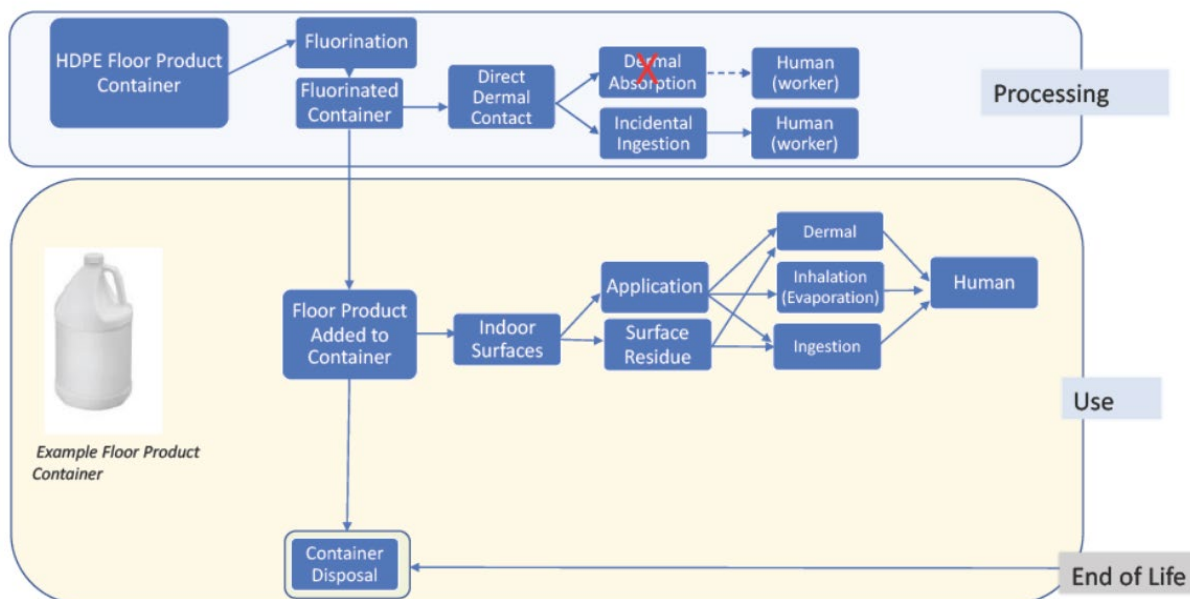
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Figure 4. Conceptual exposure model for fluorinated HDPE container used for floor products

Other household applications for fluorinated containers described in the SNUNs have similar exposure profiles. These include products used for cleaning or degreasing surfaces inside the home, such as household trigger-spray bathroom and kitchen cleaners; liquid concentrate or spray products used to seal, deodorize, or degrease carpet, hardwood, and other types of indoor flooring; products that require direct hand contact with an applicator, such as single-use furniture wipes and furniture or countertop polish or color restorer applied with a microfiber cloth or mitt; and products applied at the end of a hose, such as pesticides and herbicides applied to lawns and gardens. *See* SUMF ¶ 108 [Ex. 12 at A-257].

3. Worker and Consumer Subpopulations with Exposure to PFCAs in Containers and Their Contents

Given the many points in the container life-cycle with opportunities for exposure, there are numerous exposed worker and consumer subpopulations, such as:

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- Workers directly engaged in fluorination at Inhance’s 11 U.S. treatment facilities or exposed to LCPFACs during equipment cleanup and maintenance and handling of fluorinated containers;
- Inhance workers who ship fluorinated containers to distributors or packaging sites;
- Workers at packaging sites who fill fluorinated containers with liquid or solid products and prepare them for shipment to downstream users;
- Workers at end-use sites who handle fluorinated containers and access their contents during commercial or industrial tasks;
- Workers in container recycling and disposal operations;
- Consumers who purchase or otherwise use fluorinated containers in residences or commercial establishments and may be exposed to PFAS when handling or discarding containers and their contents;

See SUMF ¶ 110 [Ex. 18 at A-612-13].

The SNUNs do not quantify the number of exposed workers engaged in downstream processing, distribution, end-use and disposal of fluorinated containers or the number of consumers who come into contact with fluorinated containers. However, with over 200 million fluorinated containers or other items in commerce annually, workers and consumers with likely exposure to PFAS number in the tens of millions.

4. Dermal, Inhalation and Ingestion Routes of Exposure

As Drs. Phelps and DeWitt emphasize, “[t]he ubiquity of PFAS in the environment leads to exposure via ingestion, dermal absorption, and inhalation concurrently.” *See* SUMF ¶ 111 [Ex. 7 at A-70].

The description in the SNUNs of exposure pathways for various fluorinated products indicate that skin contact with containers and their contents is a common occurrence for workers and consumers who handle or use these products. *See* SUMF ¶ 114 [Ex. 12 at A-256-59, A-261-72, A-280, A-286-91, A-297, A-302; Ex. 13 at A-415, A-428]. Data from a 2012 study “suggest that PFOA is dermally absorbed and that under certain conditions the skin may be a significant route of exposure.” *See* SUMF ¶ 113 [Ex. 18 at A-614]. As emphasized by Drs. Phelps and

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DeWitt, “[t]hese data underscore that dermal absorption of PFAS – long- and short-chain – occurs and can induce adverse health outcomes.” *See* SUMF ¶ 113 [Ex. 7 at A-69].

Evaporation of the contents of consumer and commercial products stored in fluorinated containers during use can release PFAS-containing vapors or aerosol particles which are inhaled. Exposure to elevated temperatures during processing, distribution and use would increase volatilization of these products’ contents. Based on a comprehensive literature review, EPA’s Scientific Advisory Board (“SAB”) found that “[s]everal studies suggest that PFOA and its precursors in indoor air and/or house dust may be an important exposure source for some individuals” and that “PFOA is generally a dominant ionic PFAS constituent in indoor air and dust, frequently occurring above detection limits and at relatively high concentrations in all or most samples.” *See* SUMF ¶ 117 [Ex. 36, EPA SAB Report at A-891]. The Agency for Toxic Substances and Disease Registry (“ATSDR”) states that “Workers may be exposed to PFAS by inhaling them, getting them on their skin, and swallowing them, but inhaling them is the most likely route for exposure.” *See* SUMF ¶ 118 [Ex. 37, ATSDR Report at A-895].

Inhalation of PFAS can occur during use of fluorinated fuel tanks and portable fuel storage containers for engines in boats, lawn mowers and other household products. More than 5 million gas-powered mowers are sold in the United States each year. *See* SUMF ¶ 119 [Ex. 47, Cleaner Air: Gas Mower Pollution Facts at A-1189]. Inhance testing (described above) demonstrates very high concentrations of LCPFACs in fuel stored in fluorinated tanks and portable fuel containers. Exhaust from fuel combustion during engine use is likely a significant pathway for inhalation exposure to PFAS.

EPA’s 2020 “Interim Guidance on Destruction and Disposal of PFAS” recognizes that “PFAS are difficult to destroy due to the strength of the carbon-fluorine bond . . . [and that]

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[i]ncomplete destruction or recombination of reactive intermediates can potentially result in formation of new PFAS or other PICs [Products of Incomplete Combustion] of concern.” *See* SUMF ¶ 120 [Ex. 38, EPA Interim Guidance on the Destruction and Disposal of Perfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances at A-939]. Similarly, a March 2023 report of the President’s National Science and Technology Council observes that, “Incomplete thermal degradation via incineration of PFAS wastes can release toxic air pollutants.” *See* SUMF ¶ 120 [Ex. 42, White House National Science and Technology Council Report at A-1074]. Thus, PFAS in fuels are likely emitted during combustion.

5. Exposure to PFAS in recycled fluorinated plastics

Significant volumes of HDPE plastics are recycle and the recycling stream includes a large quantity of discarded fluorinated containers. *See* SUMF ¶ 121 [Ex. 40, Plastics: Material-Specific Data at A-1009-12]. Recycling facilities apply high heat to HDPE plastic wastes so they can be melted and formed into sheets or pellets that can be remolded into containers or other articles. *Id.* Thus, PFAS may be present in vapors or aerosols emitted from the facility, resulting in inhalation exposure to PFAS by workers and nearby communities. *Id.*

High levels of PFAS have been found in recycled HDPE from fluorinated containers. *See* SUMF ¶ 123 [Ex. 41, PACE Analytical Report at A-1019]. When recycled HPDE sheets or pellets containing PFAS are used in the plastic manufacturing process, the PFAS are further distributed throughout the economy, including in containers that are not fluorinated. This creates further opportunities for substantial PFAS exposure.

In sum, with over 200 million fluorinated containers in commerce annually and many pathways for exposure across the container life-cycle, exposure by workers and consumers to

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PFAS is extremely widespread. The levels of PFAS to which these populations are exposed raise serious health concerns in light of their harmful effects at low levels of exposure.

CONCLUSION

For the foregoing reasons, the Court should enter summary judgment for intervenor-plaintiffs and issue an injunction immediately restraining Inhance from violating the LCPFAC SNUR.

A proposed order is attached.

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Respectfully submitted,

/s/ Michael D. Fiorentino

Michael D. Fiorentino

LAW OFFICE OF MICHAEL D. FIORENTINO

PA Bar No. 73576

42 E. Second St., Suite 200

Media, PA 19063

(610)-566-2166

mdfiorentino@gmail.com

Attorney for Intervenor-Plaintiffs

/s/ Robert M. Sussman

Robert M. Sussman

Pro Hac Vice

SUSSMAN & ASSOCIATES

DC BAR NO. 226746

3101 Garfield Street, NW

Washington, DC 20008

(202) 716-0118

bobsussman1@comcast.net

Attorney for Intervenor-Plaintiff Center for Environmental Health and Jay De La Rosa

/s/ Paula Dinerstein

Paula Dinerstein *Pro*

Hac Vice

General Counsel

PUBLIC EMPLOYEES FOR ENVIRONMENTAL
RESPONSIBILITY

SUBJECT TO MOTION TO EXCEED PAGE AND WORD LIMIT

DC BAR NO. 333971

962 Wayne Avenue, Suite 610

Silver Spring, MD 20910

202-265-7337

pdinerstein@peer.org

*Attorney for Intervenor-Plaintiff Public Employees for
Environmental Responsibility*